Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about EES

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking EES against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What EES is used for

EES is used to:

- treat certain bacterial infections; these infections may occur in different parts of the body
- · control acne
- prevent infections in patients with a history of rheumatic disease, congenital heart disease or other acquired valvular heart disease and who may be allergic to penicillin antibiotics.

Your doctor, however, may have prescribed EES for another purpose.

Ask your doctor if you have any questions about why EES has been prescribed for you.

EES is an antibiotic that belongs to the group of medicines called macrolides. These medicines work by killing or stopping the growth of bacteria, which cause infections or make acne worse.

EES will not work against infections caused by viruses, such as colds or flu.

EES is available only with a doctor's prescription.

Before you take EES

When you must not take it

Do not take EES if you have an allergy to:

- any medicine containing erythromycin
- any of the ingredients listed at the end of this leaflet
- other antibiotics from the macrolide family, including:
 - clarithromycin
 - roxithromycin.

Some of the symptoms of an allergic reaction may include:

- · shortness of breath
- · wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

You must not take EES if:

- you are taking
 - terfenadine or astemizole
 - cisapride, pimozide or domperidone
 - class IA and III antiarrhythmics e.g. quinidine, disopyramide, procainamide, amiodarone and sotalol
 - certain neuroleptics and tri- and tetracyclic antidepressants

- arsenic trioxide, methadone, budipine, certain fluoroquinolones, imidazole antimycotics and anti-malarials e.g. petamidine i.v.
- simvastatin, lovastatin or atorvastatin
- ergotamine or dihydroergotamine
- · you have severe liver disease.
- you have heart rhythm disorders from birth or have developed it
- you have irregular heartbeat or severe chronic heart failure
- you have deficiency of potassium and magnesium in blood

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you start to take or are given EES

Tell your doctor if you have allergic to any other medicines, foods, dyes or preservatives

Tell your doctor if you have or have had any of the following medical conditions:

- · liver disease
- heart problems
- myasthenia gravis, a condition in which muscles become weak and tire easily.
- · eve disorder
- pneumonia

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking or are given EES.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with EES. These include:

- medicines used to prevent blood clotting, such as warfarin, acenocoumarol
- some medicines used for epilepsy such as phenytoin, carbamazepine, hexobarbital, phenobarbital and valproate
- theophylline, a medicine used to treat asthma
- diltiazem, verapamil, felodipine and mibefradil, medicines used to treat high blood pressure and certain heart conditions
- digoxin, a medicine used to treat heart failure
- omeprazole and cimetidine, used to prevent ulcers by reducing amount of acid produced in stomach

- ciclosporin, used to prevent organ transplant rejection or to treat certain problems with the immune system
- tacrolimus, used as an adjunct to kidney transplantation
- triazolam, zopiclone and midazolam, used to treat sleeplessness
- nefazodone and St. John's wort, medicines used to treat depression
- alprazolam used to treat anxiety disorders
- · methylprednisolone, a corticosteroid
- vinblastine, a medicine used to treat Hodgkin's Disease
- sildenafil, used to treat erectile dysfunction in adult males
- mizolastine and ebastine medicines used to treat allergies such as hay fever
- ritonavir, used to treat infections in patients with advanced HIV infection
- medicines used to treat fungal infections such as ketoconazole, itraconazole, fluconazole
- rifabutin, rifampicin, clindamycin, lincomycin, chloramphenicol, streptomycin, colistin and bactericidal beta-lactam antibiotics (e.g. penicillin, cephalosporin)
- bromocriptine, used to treat various conditions including Parkinson's Disease
- · colchicine, used for pain relief in gout
- alfentanil, a medicine used for pain relief during anaesthesia
- cilostazol, a medicine used in the treatment of painful calves, due to poor blood flow to the muscles
- diphenoxylate with atropine used to treat diarrhoea
- · opiates used as analgesics.

These medicines may be affected by EES or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist have more information on medicines to be careful with or avoid while you are taking this medicine.

How to take EES

Follow all directions given to you by your doctor or pharmacist carefully.

This may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

How much to take

The dose may be given two, three or four times a day. The usual adult dose is 5 mL of the EES 400 mg/5 mL liquid every six hours or 10 mL twice a day.

For children, the dose varies depending on their age, weight and how sick they are. Your doctor will adjust the amount or frequency of your doses according to the infection being treated and the severity of your condition.

How to take EES

EES may be taken before or after meals.

Granules: Add 77 mL of water in small volumes and shake vigorously. When reconstituted, the suspension should be refrigerated (but not frozen) and used within ten days.

Always shake the bottle well before each dose of EES granules.

Always use a medicine measure to give the exact dose of liquid medicines.

How long to take EES for

Keep taking EES until you finish the pack or bottle, or for as long as your doctor tells you.

If you are being treated for an infection, EES is usually taken for one or two weeks.

Do not stop taking EES, even if you feel better after a few days, unless advised by your doctor.

Your infection may not clear completely if you stop taking your medicine too soon.

For controlling acne, EES is normally taken for a few months.

Check with your doctor if you are not sure how long you should be taking EES.

If you forget to take EES

If it is almost time for you to take your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and continue taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

If you miss more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much EES (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much EES. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places/services handy.

If you take too much EES, you may have nausea, vomiting, hearing problems or allergic reactions.

While you are taking EES

Things you must do

If you are taking EES for an infection and your symptoms do not improve within a few days, or if they become worse, tell your doctor.

If you are about to start taking a new medicine, tell your doctor or pharmacist that you are taking EES.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking EES.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking EES, tell your doctor immediately.

If you get severe diarrhoea, tell your doctor or pharmacist immediately.

Do this even if it occurs several weeks after stopping EES. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any strong painkillers or any medicine to stop your diarrhoea without first checking with your doctor.

If you have to have any blood tests, tell your doctor you are taking EES.

It may affect the results of some laboratory tests

Things you must not do

Do not use EES to treat any other complaints unless your doctor says so.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking EES.

EES treats infections and controls acne in most people, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

While you are taking EES

Tell your doctor if you experience any of the following:

- stomach cramps and pains
- nausea, vomiting, accumulation of gas and severe diarrhoea
- · weight loss
- · fever, headache
- oral thrush
- · vaginal thrush.

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- yellowing of the eyes or skin (jaundice)
- generally feeling unwell and having poor appetite
- · loss of hearing
- ringing or buzzing in the ears
- fast, irregular or pounding heart beat
- · chest pain
- muscle pain, weakness and joint swelling
- dizziness, drowsiness, confusion, hallucinations, fits
- any type of skin rash, itching, hives, serious scaly red rash with bumps under the skin and blisters
- severe diarrhoea especially if bloody
- · any vision problem

The above list contains serious side effects that may require medical attention. Serious side effects are rare.

Stop taking EES and tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice:

 serious allergic reaction (shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin).

This is a very serious side effect. You may need urgent medical attention or hospitalisation. This side effect is very rare. Some side effects can only be found if your doctor does tests on your blood or urine.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After you have finished taking EES Tell your doctor immediately if you notice any of the following side effects, even if they occur several weeks after stopping

severe stomach or abdominal cramps

treatment with EES:

- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above.

These are rare but serious side effects. You may have a serious condition affecting your bowel and you may need urgent medical care.

Do not take any diarrhoea medicine without first checking with your doctor.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything that is making you feel unwell while you are taking, or soon after you have finished taking EES, even if it is not on this list.

After using EES

Storage

Keep your granules in the bottle until it is time to take them.

If you take the granules out of the bottle they may not keep well.

Keep EES in the refrigerator but not in the freezer. Do not use any oral liquid left in the bottle after 10 days.

Do not keep EES or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking EES, or your medicine has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

EES granules are available in two strengths:

EES granules 200 mg/5 mL and EES granules 400 mg/5 mL.

After mixing with water, the granules become a thick pink liquid.

Supplied in a 100 mL white plastic bottle.

Ingredients

The active ingredient in EES granules is erythromycin (as erythromycin ethyl succinate).

EES granules 200 mg/5 mL Each 5 mL of EES 200 mg/5 mL granules contains 200 mg erythromycin as erythromycin ethyl succinate.

EES granules 200 mg/5 mL also contain:

- carmellose sodium,
- sodium citrate dihydrate,
- aluminium magnesium silicate,
- erythrosine CI145430 (colour),
- cherry imitation flavour,
- sucrose and saccharin sodium (sweeteners).

EES granules 400 mg/5 mL

Each 5 mL of EES 400 mg/5 mL granules contains 400 mg erythromycin as erythromycin ethyl succinate.

EES 400 mg/5 mL granules also contain:

- carmellose sodium,
- sodium citrate dihydrate,
- aluminium magnesium silicate,
- citric acid,
- carmoisine CI14720 (colour),
- cherry imitation flavour,
- sucrose, saccharin sodium, and sodium cyclamate (sweeteners).

EES granules 200 mg/5 mL and EES granules 400 mg/5 mL do not contain lactose or gluten.

Sponsor

Amdipharm Mercury (Australia) Pty Ltd Level 9, 76 Berry Street North Sydney NSW 2060

Australian Registration Numbers:

EES 200 mg/5 mL granules

AUST R 173634

EES 400 mg/5 mL granules

AUST R 54456

Date of preparation

28 June 2018

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